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MERIT HEALTHCARE LIMITED

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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1. NAME OF THE MEDICINAL PRODUCT

BIOFLOR® 250 mg, powder for oral suspension.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Lyophilized *Saccharomyces boulardii* CNCM I-745.....282.50 mg
(mixture of250 mg oflyophilized yeast cells and 32.5 mg of lactose).

Excipients with known effect: lactose, fructose and sorbitol (contained in tutti frutti aroma).
For the full list of excipients: see section 6.1.

3. PHARMACEUTICAL FORM

Powder for oral suspension in sachets.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Adjuvant treatment for diarrhoea such as infectious and non specific gastroententls, antibiotic therapy associated diarrhoea, traveler's diarrhoea, chronic diarrhoea, intestinal bowel disease, diarrhoea due to *Clostridium difficile.* The treatment does not replace rehydration when this is necessary. The rehydration dose and its route of administration (oral or IV) should be adapted to the severity of the diarrhoea and to the age and state of health of the patient.

4.2. Posology and method of administration

Oral route.

Adults and children: 1 or 2 sachets

The contents of the sachet will be mixed with food or milk or water. Food, milk or water must not be too hot (over 50°C), or too cold.

Due to a risk of airborne contamination, sachets should not be opened in patients rooms. Healthcare providers should wear gloves during handling of probiotics for administration, then promptly discard the gloves and properly wash their hands (see section 4.4).

4.3. Contraindications

- Hypersensitivity to one of the components;
- Patient with central venous catheter;
- Critically ill patients or immunocompromised patients due to a risk of fungaemia (see section 4.4).

4.4. Special warnings and special precautions for use.

BIOFLOR® 250 mg contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

BIOFLOR® 250 mg contains fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

If symptoms persist for more than 2 days of treatment at usual posology, the therapeutic approach will be re-evaluated.

The treatment does not replace rehydration when this is necessary. The rehydration dose and its route of administration (oral-IV) should be adapted to the severity of the diarrhoea and to the age and state of health of the patient.

There have been very rare cases of fungaemia (and blood cultures positive for Saccharomyces strains) and sepsis reported mostly in patients with central venous catheter, critically ill or imrnunocompromised patients, most often resulting in pyrexia. In most cases, the outcome has been satisfactory after cessation of treatment by *Saccharomyces boulardii,* administration of antifungal treatment and removal of the catheter when necessary. However, the outcome was fatal in some critically ill patients (see sections 4.3 and 4.8).
As with all medicines made from living micro-organisms, special attention must be paid to the handling of the product in the presence of patients mainly with central venous catheter but also with peripheral catheter, even not treated with *Saccharomyces boulardii,* in order to avoid any contamination by hands and/or the spread of microorganisms by air (see section 4.2).

This drug is a complement of dietetic rules:
• rehydration by abundant, salted or sweetened drinks, in order to compensate for the loss of liquid due to diarrhoea (the average daily ration of water in adult is 2 liters).
• to feed during the diarrhoea:
- by excluding certain supply and particularly fruits, green vegetables, spiced dishes, as well as food and frozen drinks,
- by privileging roasted meats and rice.

BIOFLOR® 250 mg contains living cells. This drug should therefore not be mixed with very hot (over 50°C), iced or alcoholic drinks or food.

4.5. Interaction with other medicinal products and other forms of interaction

Because of its fungal nature, BIOFLOR® 250 mg must not be administered with systemic or oral antifungal drugs.

4.6. Pregnancy and lactation

There are no reliable animal teratogenesis data.
Clinically, no malformative nor fetotoxic effect has been reported to date.
However, monitoring of pregnancies exposed to this medicine is insufficient to rule out any risk.
Hence, as a precautionary measure, it is preferable to avoid using this medicine during pregnancy.
In the absence of data, it is preferable to avoid using this medicine during lactation.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

The side effects which have been reported are classified hereafter by system-organ class and by frequency defined as: very common (2:1/10), common (2: 1/100, < 1/10), uncommon (2: 1/1,000, < 1/100), rare (2: 1/10,000, < 1/1,000), very rare(< 1/10,000) and not known (cannot be estimated from the available data).

Within each frequency grouping, adverse reactions are presented in the order of decreasing senousness.

System Organ Class	Rare	Very rare	Not known
Skin and subcutaneous tissue disorders		Allergic reactions: pruritus, wheal formation (urticaria), skin rash, either locally restricted or affecting the entire body (local or generalized exanthema), swelling of the connective tissue of the face (angioedema).	
Immune system disorders		Anaphylactic reaction or even shock	
Gastrointestinal disorders	Flatulence		Constipation
Infections and infestations		Fungemia in patients with a central venous catheter and in critically ill or immunocompromised patients (see section 4.4)	Sepsis in critically ill or immunocompromised patients (see section 4.4)

4.9. Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamics properties

ANTI-DIARRHOEA

Replacement flora

(A: digestive system and metabolism) ATC code: A07FA02

5.2. Pharmacokinetic properties

After repeated oral doses, *Saccharomyces boulardii* transits in the digestive tract without colonizing it.

Saccharomyces boulardii is no longer present in the stools 2 to 5 days after discontinuation of treatment.

5.3. Preclinical safety data

There is no animal toxicity.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Lactose, fructose, anhydrous colloidal silica, tutti frutti aroma (containing sorbitol).

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years.

6.4. Special precautions for storage

Store away from humidity at a temperature below 30°C.

6.5. Nature and contents of container (and special equipment for use, administration or implantation)

Cardboard boxes containing sachets made of paper-aluminium-polyethylene laminate.
Box of 10 sachets.

6.6. Special precautions for disposal (and other handling)

No special requirements.

7. APPLICANT/MANUFACTURER

Applicant
BIOCODEX France
7, avenue Gallieni
94 250 GENTILLY, France

Manufacturer:
BIOCODEX
1 avenue Blaise Pascal
60000 BEAUVAIS, France

8 MARKETING AUTHORIZATION NUMBER(S)

9 DATE OF FIRST AUTHORIZATION/ RENEWAL OF THE MEDICINAL PRODUCT

Marketing Authorisation granted on

10 DATE OF REVISION OF THE TEXT

Last revision was on January 2021

~~CONDITIONS OF PRESCRIPTION AND DELIVERY~~

Prescription only medicine